K123766

510(k) Summary

1. Submitter's Name:
Novo Nordisk Inc.
P.O. Box 846
Plainsboro, NJ 08536

AUG 15 2013

Contact Person
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Senior Director Regulatory Affairs
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Date Prepared: June 19, 2013

2. Device Name:

Proprietary Name:	NovoPen Echo®
Common Name:	Dial-A-Dose Insulin Delivery Device (Pen Injector)
Classification Name:	Syringe/Piston (FMF)
Regulation:	21 CFR 880.5860
Class:	Class II

3. Predicate Device:

510(k) cleared device (Primary Predicate Device)

Manufacturer:	Novo Nordisk
Proprietary Name:	K010359 Innovo®

4. Device Description:

The NovoPen Echo® is a reusable mechanical pen-injector capable of injecting a dose of up to 30 units of insulin, in half unit increments, from a Novo Nordisk 3.0 mL insulin cartridge. The intended dose is mechanically set by rotating a dose button. The insulin is injected by depressing the dose button which via mechanical coupling causes the piston in the insulin cartridge to move forward thereby expelling the intended dose. The device has a memory function and liquid crystal display that allows the user to review the units of the last dose and the number of hours that have elapsed since the last dose was taken. Rotation of the dose button during dose setting causes a

sensor to rotate within a coded cylinder. The movement detected by this sensor is stored for later display on the liquid crystal display in the dosage selector module as the number of units injected. The pen-injector is intended for use with Novo Nordisk 3.0 mL insulin cartridges and single-use, detachable and disposable pen needle (supplied separately by Novo Nordisk).

5. Intended Use including Indication for Use:

The Novo Pen Echo is a re-usable pen injector designed for single-patient use by diabetics for the self-injection of a desired dose of insulin. The pen injector uses PenFill 3.0 mL cartridges of Novo Nordisk insulin and a single use detachable and disposable pen needle (supplied separately). The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one half (1/2) unit increments.

6. Technological Characteristics:

The NovoPen Echo® is considered substantially equivalent to the predicate device in intended use, principle of operation, memory function, energy source and performance. The memory function of the predicate device has identical functionality as the NovoPen Echo. The injection technique used to administer insulin is the same for each device. Each device requires a needle to penetrate the subcutaneous layer of tissue, an insulin source and a plunger to push the insulin from the source, through the needle and into the subcutaneous layer of tissue. Each device is capable of multiple injections from a single insulin source (cartridge).

7. Testing

Performance Data:

The results of design verification testing has documented that the NovoPen Echo® meets all its design requirements and complies with the requirements specified in ISO11608-1 Pen-injectors for medical use – Part 1: Pen-injectors – Requirements and test methods.

The results of Human Factor testing has documented that the NovoPen Echo® is safe to use by the intended users in the intended environment for the intended use.

Shelf Life:

The NovoPen Echo® has an in-use lifetime of 5 years provided that the pen is taken into use within two years of the production date. The NovoPen Echo® informs the user via the memory display when the pen has reached its end of life.

8. Conclusions:

In conclusion, the results of the testing demonstrate that NovoPen Echo is as safe and effective and performs as well as the predicate device.

The results of the testing to voluntary standards provide additional evidence that NovoPen Echo is substantially equivalent to the predicate device in terms of safety, efficacy and performance.

The differences between NovoPen Echo® and the predicate device do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2013

Novo Nordisk, Incorporated
Mr. Rick Spring
Associate Director, Regulatory Affairs
P.O. Box 846
PLAINSBORO NJ 08536

Re: K123766
Trade/Device Name: NovoPen Echo®
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 22, 2013
Received: July 23, 2013

Dear Mr. Spring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123766

Device Name: NovoPen Echo®

Indications For Use: The NovoPen Echo® is a re-useable pen injector designed for single patient use by diabetics for the self-injection of a desired dose of insulin. The pen injector uses PenFill® 3 mL cartridges of Novo Nordisk insulin and a single use detachable and disposable pen needle (supplied separately). The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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